REMARKS

The Final Office Action of May 10, 2011, has been carefully considered.

Claim 16 has been amended to recite that the needle comprises three or four reinforcement stainless steel wires, which amendment is fully supported by the original disclosure.

Claims 23-24 were rejected under 35 USC 112, first paragraph, as being unsupported by the specification with regard to the term "piston", and the drawing was objected to under 37 CFR 1.83(a) as failing to show the piston.

The Applicant respectfully submits that the term "piston" as part of the syringe structure is fully supported by the original disclosure on page 7, lines 21-27. The structure of a syringe is well known to a person or ordinary skill in the art and, moreover, the present invention bears on the needle structure, and not on the structure of the components of the syringe itself.

However, in order to advance prosecution of this case, claim 23 has been amended so that it no longer refers to a piston.

Presently amended claim 23 now recites an injection syringe comprising a needle according to claim 1,

It is indeed apparent from the application as filed that the invention lies in the needle, and not in a syringe, but that the use of a needle is with a syringe. Thus the claiming of an

injection syringe comprising the needle of claim 16 is believed to be proper.

In view of the above amendments and remarks, it is respectfully submitted that the rejection of claims 23-24 under 35 USC 112, first paragraph, and the objection to the drawing under 37 CFR 1.83(a), are now moot. Favorable reconsideration and withdrawal of the rejection and objection are thus urged.

Claims 16-21 are rejected under 35 USC 103(a) as being unpatentable over Yoshikawa et al. (US 5,637,399, hereinafter "Yoshikawa") in view of Preissman (US 6,348,055).

More particularly, the Patent Office mentions on page 4 of the Final office action that the needle has a wall in contact with the central lumen comprising a polyaryletherketone (PEEK), the needle further comprising at least three reinforcement wires embedded in the polymer and extending parallel to the longitudinal axis, and being even-tensioned throughout the length of hollow body (col. 1, lines 47, through col. 2, line 4), and distributed such that any pair of wires defines an identical center angle (col. 3, lines 40-50).

More particularly, the Examiner takes the position (page 4 of the final Office action) that Yoshikawa discloses a needle having a wall comprising a polyaryletherketone (PEEK) in contact with the central lumen of the needle, the needle

further comprising at least three reinforcement wires embedded in the polymer, and extending parallel to the longitudinal axis of the needle, and being even-tensioned throughout the length of hollow body (in reference to Yoshikawa at col. 1, lines 47 through col. 2, line 4), and distributed such that any pair of wires defines an identical center angle (with reference to Yoshikawa at col. 3, lines 40-50).

The Applicant respectfully disagrees with the position taken by the Patent Office.

Indeed, although Yoshikawa discloses a synthetic resin needle which may be made with a number of synthetic resins, including PEEK (col. 2, lines 14 and 27), the resin is actually reinforced with <u>combustible fibers</u> (col. 2 lines 30-31).

Further the fibers of Yoshikawa, depending of the kind of the synthetic resin used, represent <u>from 10 to 80% by volume</u>, preferably 30 to 80% by volume, more preferably 40 to 70% by volume of the resin material (see col. 2, lines 51-56 of Yoshikawa).

To reach such a level of volume, bundles of thousands of fibers would have to be used, as shown in the examples. For instance, in Example 1 of Yoshikawa, a bundle of 7,800 carbon fibers is used, the fibers being <u>uniformly</u> dispersed, and the synthetic resin is introduced so as to impregnate

the carbon fibers (see col. 3, lines 65-66, col. 4, lines 1-4; and col. 4, lines 6-11).

To further differentiate the claimed invention from Yoshikawa, claim 16 has been amended to recite three or four reinforcement stainless steel wires.

Yoshikawa clearly fails to teach or suggest the use of three or four reinforcement stainless steel wires, and this constitutes an essential technical difference between Yoshikawa and what the Applicant is claiming.

It is clear that the thousands of fibers uniformly distributed throughout the needle resin body of Yoshikawa's needle cannot meet Applicant's claim requirement that any pair of the wires define an identical center angle. Furthermore, no real center angle can be defined for most of the fibers of Yoshikawa.

In addition, as discussed above, the Yoshikawa reinforcing fibers are synthetic and are combustible fibers.

In the context of Applicant's invention, the three or four reinforcement stainless steel wires may be depyrogenized without becoming deformed, these being important properties of the needle of the invention (see specification at page 2, lines 1 to 13). These properties result from a combination of the PEEK material with the reinforcing wires located equidistantly (see page 2, line

34, to page 3, line 2; and page 6, lines 14 to 31), the best embodiment being a wire made of 316 stainless steel (page 6, lines 29-31; and claim 18).

With the combustible fibers required by Yoshikawa, however, it is not possible to obtain a resistance to deformation during depyrogenizing, contrary to the situation obtained in the present invention.

According to Applicant's invention, the wires, being equidistantly disposed, have a dilation coefficient similar to the dilation coefficient of PEEK, which cannot be said of the combustible fibers used by Yoshikawa, such as carbon fibers, or others.

Accordingly, with Applicant's invention, during heating up to 250°C for the purposes of sterilizing or depyrogenizing, no torsion or deformation of the invention needle is noticed.

In view of all of the above, it is submitted that Yoshikawa does not disclose or suggest the presently claimed invention.

The Preissman reference does not fill the gaps left by Yoshikawa.

Preissman relates to a non-compliant system for delivery of implant material from a high pressure applicator to an implant delivery device. As such, there exists no

motivation for a person or ordinary skill in the art to modify the needle of Yoshikawa with Preissman's teaching of a non-compliant system.

Furthermore, Preissman teaches, in the embodiment of Figures 8 and 9, a tubing 70 which can be made of different polymers, including PEEK. However, when the material is made of PEEK, no reinforcing coil is used (see col. 9, lines 44-45). Accordingly, Preissman teaches away from the invention by teaching that when the tubing is made of PEEK, no reinforcing coil has to be present.

In view of the above remarks, it is submitted that a combination of Yoshikawa and Preissman would not result in the Applicant's invention, especially in the light of Preissman's disclosure that no reinforcing coil is used with PEEK. This would suggest to a person of ordinary skill in the art that no reinforcing coil should be used with PEEK.

In view of all of the above, it is submitted that the rejection under 35 U.S.C. 103(a) is unsustainable, and should be favorably reconsidered and withdrawn.

Applicant submits that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Applicant hereby petitions the Commissioner for Patents to extend the time for reply to the Final Office action dated

May 10, 2011, for one (1) month from September 10, 2011, to October 10, 2011. Payment is being made by electronic funds along with the filing of this paper.

Respectfully submitted,

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